UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,551	06/30/2003	Susan I. Shelso	S63.2-10691	5002

490 7590 04/07/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,551	SHELSO, SUSAN I.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/29/03 & 3/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it contains legal phraseology ("comprises" lines 6 and 8). Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claim 21 is objected to because of the following informalities: claim 21 is dependent on claim 1, making it identical to claim 6. For examination purposes, claim 21 has been interpreted as being dependent on claim 11, not claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 6-12, 14-15, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et al. (U.S. 2003/0212451 A1).

Regarding claim 1, Cox et al. disclose a grip (Figure 18, element 100) constructed from a polymeric material (paragraph 79) comprising a body region (40), a first end (adjacent to element 42), and a second end (108), with the diameter of the first end being greater than the diameter of the second end. Regarding claim 2, Figure 18 shows a hub region (42) adjacent to the first end, with the diameter of the hub being greater than the diameter of the first end. Regarding claim 3, Figure 18 shows a grip (100) substantially tapered from the first end (adjacent to element 42) to the second end (108). Regarding claim 6, Cox et al. teach a portion of the grip can be made from "poly-ether-block-amide" or other similar polymeric material or alloy suitable for use (paragraph 79). Regarding claim 7, Cox et al. teach a "radiopaque" material can be compounded with a polymeric material to form a portion of the grip (paragraph 79). Regarding claim 8, Figure 18 shows a grip (100) engaged to an inner shaft portion (35) of a catheter. Regarding claim 9, Figure 18 shows a grip (100) on at least a portion of a stent mounting region. Regarding claim 10, Figure 18 shows an expanded stent (80). The stent in an unexpanded state would look similar to the unexpanded stent (10) in

Figure 1, in which the unexpanded stent (10) is engaged to at least a portion of the body region (40) of a grip.

Regarding claim 11, Figure 18 shows a catheter having an inner shaft (35), a grip (100) engaged thereto, and a retractable sheath (52). Cox et al. disclose a grip (100) constructed from a polymeric material (paragraph 79) comprising a body region (40), a first end (adjacent to element 42), and a second end (108), with the diameter of the first end being greater than the diameter of the second end. Figure 18 shows an expanded stent (80). The stent in an unexpanded state would look similar to the unexpanded stent (10) in Figure 1, in which the unexpanded stent (10) is being disposed about a portion of the inner shaft (35) and engaged to at least a portion of the body region (40) of at least one grip. A retractable sheath (52) overlies the unexpanded stent (10), and when the retractable sheath is retracted off of the stent, the stent expands (Figure 18). Regarding claim 12, Figure 18 shows a stent (80) comprising a plurality of struts. Regarding claim 14, Figure 18 shows at least one grip (100) comprising a hub region (42) adjacent to the first end, with the diameter of the hub being greater than the diameter of the first end. Figure 1 shows an unexpanded stent (10) being positioned adjacent to the hub (42). Regarding claim 15, Figure 18 shows at least one grip (100) substantially tapered from the first end (adjacent to element 42) to the second end (108). Regarding claim 21, Cox et al. teach a portion of at least one grip can be made from "poly-ether-block-amide" or other similar polymeric material or alloy suitable for use (paragraph 79). Regarding claim 22, Cox et al. teach a "radiopaque" material can be compounded with a polymeric material to form a portion of at least one grip (paragraph 79).

Regarding claim 23, Figure 18 shows minimal space between an inner shaft portion (35) of a catheter and a retractable sheath (52). Regarding claim 24, Cox et al. disclose at least one grip (Figure 18, element 100) engaged to a portion of a catheter shaft (35); the at least one grip (100) constructed from a polymeric material (paragraph 79) comprising a body region (40), a first end (adjacent to element 42), and a second end (108), with the diameter of the first end being greater than the diameter of the second end. Figure 18 shows an expanded stent (80). The stent in an unexpanded state would look similar to the unexpanded stent (10) in Figure 1, in which the unexpanded stent (10) is engaged to at least a portion of the body region (40) of at least one grip. A retractable sheath (52) overlies the unexpanded stent (10), and when the retractable sheath is retracted off of the stent, the stent expands (Figure 18).

6. Claims 11-13 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Gunderson (U.S. 2004/0204749 A1).

Regarding claim 11, Figure 9 shows a catheter (18) having an inner shaft (20), a grip (10) engaged thereto, and a retractable sheath (52). Gunderson discloses a grip (10), which he refers to as a "band", constructed from a polymer material (paragraph 37). The body region is considered to be the portion adjacent to the first end (Figure 5, element 42) extending outward towards a second end (not labeled). Gunderson discloses a grip (10) may be provided with one or more flaps (paragraph 40), which would give the first end (42) a larger diameter than the second end. Figure 10 shows an expanded stent (26), and Figure 8 shows the stent in an unexpanded state, in which the unexpanded stent (26) is disposed about a portion of the inner shaft (20) and engaged

to at least a portion of the body region of at least one grip (10). A retractable sheath (52) overlies the unexpanded stent (26), and when the retractable sheath is retracted off of the stent, the stent expands (Figure 10). Regarding claim 12, Figure 3 shows a stent (26) comprising a plurality of struts (28). Regarding claim 13, Gunderson teaches that many stent delivery systems exert forces on the stent during withdrawal of the sheath from about the stent (paragraph 9). To prevent the stent from being drawn longitudinally (i.e. to reduce the "longitudinal force the catheter exerts on the individual struts" of the stent), many delivery systems provide the catheter shaft with one or more "bumpers or hubs" (paragraph 8 and Figure 9). Regarding claim 16, Gunderson teaches that one or more grips (10) may be disposed about the catheter under the stent (paragraph 16). Figure 8 shows a first grip (10) and a second grip (not labeled), with the second end of the body region of the first grip being substantially adjacent to the second end of the body region of the second grip. Regarding claim 17, Figure 8 shows a stent (26) comprising a first end portion, second end portion, and a body portion therebetween. In the unexpanded state the first end portion of the stent (26) is engaged to at least a portion of the body region of the first grip (10), and the second end portion of the stent being engaged to at least a portion of the body region of the second grip (not labeled). Regarding claim 18, Figure 8 shows an unexpanded stent (26), wherein the body portion of the stent overlies the second end of the body region of the first grip (10) and the second end of the body region of the second grip (not labeled).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4-5 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. in view of Helgerson et al. (Patent No. 6,149,996).

Regarding claims 4-5, Cox et al. disclose a grip as recited in claim 1, but do not disclose the hardness of the grip. Helgerson et al. teach putting a "molded tip" on tubing for use in a stent delivery device (Figure1). As noted therein, the cured molded tip is flexible (column 2, lines 19-20) in order to facilitate stent delivery, having a Shore hardness of about 70A to about 110A (column 2, lines 52-56). Therefore, to construct the grip of Cox et al. with a hardness of about 60A to about 90A, or about 70A to about 90A, would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a flexible grip that facilitates stent delivery.

Regarding claims 19-20, Cox et al. disclose a stent delivery system as recited in claims 11-12, but do not disclose the hardness of the grip. Helgerson et al. teach putting a "molded tip" on tubing for use in a stent delivery device (Figure1). As noted therein, the cured molded tip is flexible (column 2, lines 19-20) in order to facilitate stent delivery, having a Shore hardness of about 70A to about 110A (column 2, lines 52-56). Therefore, to construct the grip of Cox et al. with a hardness of about 60A to about 90A, or about 70A to about 90A, would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a flexible grip that facilitates stent delivery.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 7:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Tyson
March 27, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/2/06